

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA,)
ex rel.)
JULIE LONG,) Civil Action
)
Plaintiffs) No. 16-12182-FDS
)
vs.)
)
JANSSEN BIOTECH, INC.,)
Defendant)

BEFORE: CHIEF JUDGE F. DENNIS SAYLOR, IV

MOTION TO DISMISS

John Joseph Moakley United States Courthouse
1 Courthouse Way
Boston, MA 02210

May 29, 2020
10:00 a.m.

Valerie A. O'Hara, FCRR, RPR
Official Court Reporter
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1 PROCEEDINGS

2 THE CLERK: Court is now in session in the matter
3 of United States of America vs. Janssen Biotech, Matter
4 Number 16-12182.

5 Parties are reminded that recording and
6 rebroadcasting of this hearing is prohibited and may result
7 in sanctions.

8 Would counsel please identify themselves for the
9 record beginning with plaintiff's counsel.

09:59AM 10 MR. PRESTON: Good morning, your Honor, this is
11 Casey Preston from Cohen, Milstein representing the relator,
12 Julie Long.

13 THE COURT: All right, good morning.

14 MR. SHAPIRO: This is Jonathan Shapiro representing
15 the relator.

16 THE COURT: Good morning.

17 MR. POSNER: And for the defendant, this is
18 Ethan Posner from Covington & Burling for the defendant, and
19 I think there are a couple of my colleagues on as well.

10:00AM 20 THE COURT: All right. This is a hearing on the
21 motion to dismiss. We're conducting this by telephone. Let
22 me begin by confirming that we have our court reporter with
23 us and that she can hear us.

24 COURT REPORTER: Yes, Judge.

25 THE COURT: Okay. So, Mr. Posner, are you taking

1 the lead? It's your motion, I think?

2 MR. POSNER: Yes, thank you, your Honor. And
3 thank you to chambers for setting up this call.

4 So, your Honor, there's a lot of paper here, we
5 recognize that, but this question of product support service
6 is a familiar one for the OIG and the government. A number
7 of relators have attempted to transform these services,
8 which I understand they sound valuable at first read into
9 kickbacks, but I think the IOG advisory opinions cite to
10 several. I'll specify which ones I'm talking about.

11 On the two cases on which we rely, the *Forney* case
12 and the *Suarez* case, I think provide a framework to analyze
13 the question. Under the OIG guidance, these kind of support
14 services do not constitute remuneration, or at least do not
15 implicate the anti-kickback statute. They do not provide
16 substantial and independent value, so you see these OIG
17 opinions that state that extensive product services do not
18 implicate the anti-kickback statute.

19 There are a number of OIG opinions on insurance and
20 billing and coding and reimbursement assistance, calling
21 insurers, helping physician offices with the kinds of coding
22 and reimbursement and prior authorization paperwork, with
23 which we may all be personally familiar.

24 There are OIG opinions about, you know, kiosks in
25 pharmaceutical, in physician offices, or even providing

1 personnel in the office for training and education, so the
2 OIG has recognized as long as those products, which cost the
3 pharmaceutical companies a lot of money -- although the
4 inquiry isn't whether it costs them money, as long as it is
5 tied to the product. I'll get into that in a minute --
6 don't provide the kind of substantial or value independent
7 from the product that would implicate the anti-kickback
8 statute.

9 Obviously, the courts, at least twice, have applied
10 the OIG guidance. The *Forney* case involved, you know, free
11 staff and clinics and device checks with specific patients.
12 The relator said that was all free labor and helped the
13 physicians' bottom line.

14 In the *Suarez* case, the nurses actually came into
15 the physician office and worked with the patients and the
16 physician staff. It's called the Ambassador Program. It
17 helped with insurance program coverage. They fielded all
18 sorts of administrative questions, and when you look at the
19 OIG opinions and you look at these two cases, they cover,
20 you know, all the kinds of coding and billing and
21 administrative support about which the relator has
22 complained here.

23 They all involved former company employees working
24 directly sometimes for years with physicians, physician
25 office staff to assist in the administration of the

1 medicines and getting them billed and coded.

2 Now, another aspect that we have here that we
3 didn't have in *Suarez* or *Forney* or even the OIG guidance is
4 that some of the core issues about which relator complains
5 are publicly available.

6 Now, I understand that we provided a lot of this to
7 the Court, too much, but let me cite some very specific
8 items that are in the public domain.

9 There is an article in the International Journal of
10:04AM 10 MS Care. It's Exhibit F, page 27, and it talks about all of
11 these, it advises physicians about in-office infusion
12 suites, which is what this case is about, and it gives them
13 all sorts of advice about space and staffing and how to do
14 this and how do you buy and bill and how do you bill
15 Medicare and what codes should you use, and it's got that
16 kind of public advice, which you see in the J & J materials
17 that are cited in the complaint and that we think are
18 appropriate for this Court's consideration at this stage.

19 There's also a chart about an infusion suite in the
10:05AM 20 J & J materials, and if you look at Exhibit H, page 5, you
21 will see literally the same chart about an infusion suite,
22 you should put the nurses here, and you should put the lab
23 there, and here's how you arrange your billing and coding
24 personnel and your clinical area and here's how many chairs.
25 It's literally the same chart that you see in the J & J

1 materials.

2 So, you know, this question about infusible suites,
3 which, obviously, the rheumatologists and the
4 gastroenterologists needed because Remicade and then the
5 other medicines, Simponi ARIA, which are RA and Crohn's
6 disease and all sorts of colitis medicines were the first
7 kinds of infusible products, and the relator makes the same
8 allegations about value that the relators made in the *Forney*
9 and *Suarez* cases.

10:06AM 10 THE COURT: Let me interject, if I can. This
11 information you say is publicly available. Can I consider
12 that on a Rule 12(b)(6) motion or is that more appropriately
13 addressed through summary judgment?

14 MR. POSNER: Well, there's a few reasons that we
15 believe you can, your Honor. Number 1, we're comparing it
16 to items in the complaint, which your Honor can consider the
17 items in the complaint under Rule 12, and what we're doing
18 is using them for an incredibly narrow purpose, just using
19 them to show, and I do think your Honor can take judicial
10:06AM 20 notice of a journal article or something that we've provided
21 a website cite for.

22 We do think your Honor in this narrow instance can
23 take notice of comparing something in the complaint, it's
24 cited in the complaint, it's certainly fair game under
25 Rule 12, and then comparing it to a publicly available item

1 like a journal article, that we do think, since we're not
2 using the journal article for a wider purpose, we're just
3 using it to show it was public, and here's what it says.

4 And I don't think there's any dispute that the
5 journal article is accurate or doesn't say what it says. I
6 mean, it's a published journal article, so in that sense, we
7 do think your Honor can consider this under Rule 12.

8 I understand that we added a lot of paper of
9 publicly, you know, publicly-available material, and I'm
10:07AM 10 trying to distill all this to just a few items, but we do
11 think your Honor can for these narrow purposes under Rule 12
12 use that.

13 And, obviously, we're citing the OIG opinions as
14 well, and the courts have, you know, implemented and used
15 those under Rule 12 as well.

16 You know, the *Forney* and *Suarez* cases that use the
17 OIG opinions, we have more here with the publicly-available
18 stuff, but what those cases did was they dealt with the same
19 arguments that relator is making about the business is more
10:08AM 20 profitable, Janssen devoted people and resources to the
21 physicians, or, well, the physicians might pay consultants
22 for this, but the Court found that that was too conclusory,
23 and, obviously, that's what we think as well, and those
24 cases, I mean, those were nurses in the office fielding
25 administrative questions, in *Suarez*, billing and

1 reimbursement support, and, of course, the next step is
2 whether the services have any independent value, and the OIG
3 and its opinion in 2000, it's called 00-10 said that the
4 drug companies often offer free assistance to physicians,
5 insurance coverage, billing, reimbursement, and these
6 services, the OIG said, have no value apart from the
7 products, they're properly considered part of the products,
8 and they have no independent value.

9 The test is whether they're linked, and here these
10:09AM 10 services are obviously linked to Remicade and Simponi, they
11 were the only infusible medicines for a long time in these
12 therapeutic areas. There was no other reasons to offer
13 these services but for these products, and there was no
14 value outside the product.

15 There is a conclusory allegation that, well, in
16 theory the physicians could use these infusion suites for
17 other infusible medications, but there's just that
18 conclusory allegation.

19 The relator says she worked at the company for many
10:10AM 20 years. She said she had these unidentified patient counts,
21 and she worked closely with them, but she doesn't have any
22 example where these physician offices with whom she worked
23 closely for many years, according to the complaint, actually
24 used these infusion suites or any of the advice that sort of
25 standard reimbursement and infusion suite advice that was

1 provided for any other medicines.

2 And *Forney* rejected a conclusory allegation just
3 like this, where theoretically, you could use this kind of
4 advice or service for some other medicine, but there's no
5 evidence of that here, there's no specific allegation at
6 all.

7 Let me turn briefly, if I can, to 9(b). I reread
8 your Honor's ruling in the *Hagerty* case a few years ago.
9 It's a *qui tam* like this one.

10:11AM 10 THE COURT: I always tell lawyers I hope you have
11 better authority than me.

12 MR. PRESTON: Yeah, well, this was pretty on point
13 in our view, your Honor. We -- I mean, as your Honor will
14 recall, what, you know, there was a lot -- there were a lot
15 of allegations about the defendant's misconduct, as there is
16 in this case, and as your Honor noted, look, any
17 pharmaceutical case is going to have, you know, Medicare and
18 Medicaid claims arising from whatever the scheme that is
19 alleged, and your Honor found that the details on the scheme
10:11AM 20 were enough.

21 We're not contesting the very narrow way under
22 Rule 12 that the allegations about the advice at large are
23 not enough under 9(b). The Court, of course, focused on
24 there was that there was nothing about the specific claims.

25 Now, in the *Forney* case, the complaint named the

1 specific physicians, which we don't have here but nothing
2 about specific patients or specific claims. Of course, here
3 we have nine unidentified accounts, A through H in paragraph
4 176, and there's information about what J & J provided, what
5 kind of service, you know, they had a sales rep, the sales
6 rep was really helpful, this was the kind of business advice
7 that these accounts got, and paragraph 176C is the one where
8 the relator says, look, I worked with this account for 15
9 years.

10:12AM 10 There's no -- there's not a single claim. All
11 paragraphs 191 to 193 say is that these unnamed physicians,
12 I have no idea who they are, submitted lots of claims to
13 Medicare, but I have no idea which ones were false. There's
14 no specific claim, and so I think, like the relator in the
15 *Hagerty* case, what you have are allegations, you have
16 statistics about Medicare claims generally.

17 Your Honor concluded in the *Hagerty* case that the
18 statistics were not focused or precise, and I do think
19 that's what we have here, we obviously have no date, no
10:13AM 20 patients.

21 You know, we all understand that logically, yes,
22 Remicade was a revolutionary medicine, lots of patients used
23 it, Medicare and Medicaid logically must have reimbursed for
24 loss of those claims, but the Court said the logic isn't
25 enough, and this is already the second-amended complaint.

1 This is the third try here, and we still have no
2 claims data at all. We have no -- there's nothing in here
3 about how the services linked to any claims, which specific
4 claims there were, we just have the general allegation that
5 these were rheumatologists, I worked with them for years,
6 they submitted thousands of claims in Remicade, and we don't
7 think that is enough under Rule 9(b).

8 So, your Honor, we think even though there's a lot
9 of paper here that if you take the five or six or seven OIG
10:14AM 10 opinions that we cite, and we think we cite the Westlaw
11 cites for those, and you look at just couple of
12 publicly-available items, look at the two cases that already
13 provides the framework to dismiss these under Rule 12, as
14 the courts did in *Forney* and *Suarez*.

15 THE COURT: Okay. All right. Who's going
16 to -- I'm sorry, Mr. Posner, were you finished?

17 MR. POSNER: I am, unless your Honor has any
18 questions for me. I guess I would reserve.

19 THE COURT: Yes, of course.

10:15AM 20 MR. POSNER: Not that I have sort of the clock is
21 running, but I guess I would reserve if your Honor would
22 permit me to respond briefly to whatever the relator's
23 counsel says.

24 THE COURT: Yes, of course. Mr. Preston, are you
25 going to take the lead?

1 MR. PRESTON: Yes, your Honor.

2 THE COURT: Okay.

3 MR. PRESTON: Good morning, your Honor, on behalf
4 of plaintiff relator Julie Long, may it please the Court,
5 your Honor, I'm going to first address Janssen's argument
6 that the relators' complaint does not allege illegal
7 remuneration.

8 In making this argument, Janssen is suggesting that
9 the Court should accept as true its version of the facts,
10:15AM 10 not the facts in the complaint.

11 As your Honor knows, Congress intended for the term
12 "remuneration" to have broad application such that it covers
13 the transfer of anything of value in any form or manner
14 whatsoever.

15 HHS OIG has issued guidance to healthcare industry
16 warning about arrangements that could involve the offer of
17 payment of remuneration that would violate the anti-kickback
18 statute under the OIG guidance that Janssen Biotech's
19 counsel has referenced, but they are focused on one
10:16AM 20 paragraph of one specific guidance related to product
21 support, but there's substantial other guidance that OIG has
22 issued concerning remuneration that Janssen Biotech
23 overlooks.

24 That guidance to the healthcare industry warned
25 about arrangements that are gifts or payments of kind, and

1 that is what we allege that the business services are here.
2 These are not product support. Under the OIG guidance from
3 1994 cited in Ms. Long's briefing, the gifts or payments in
4 kind violate the anti-kickback statute when they are
5 provided to a person or physician that generates business
6 for the drug manufacturer.

7 Janssen services specifically targeted high
8 prescribers, not all physicians, just the top accounts or
9 accounts that have the potential to be the top account.

10:17AM 10 That's not product support.

11 The very nature of these services aren't related to
12 a specific product, they are related to increasing infusion
13 volume by helping accounts build infusion suites hoping
14 accounts grow infusion suites.

15 Under the OIG guidance, the services merely have to
16 be more than nominal in value. As explained in Ms. Long's
17 briefing, the complaint alleges specific facts that
18 plausibly show that the primary purpose of the ABS program
19 is to induce growth and account infusion businesses and in
10:18AM 20 turn induce purchases and infusions of Remicade and Simponi
21 ARIA.

22 Those allegations include the frequency and level
23 of the infusion business support that Janssen Biotech
24 provided. It's based upon sale volume. Many of the
25 services that are specifically designed to help grow IO

1 accounts, the infusion office suites.

2 Janssen directs the area business specialists, this
3 team of special employees who only provide these services,
4 and they don't just provide them by the presentation that
5 Janssen has submitted to the Court, which is, you know, a
6 few of the many presentations they provide.

7 They provide -- these are in-person individualized
8 consultations regarding operation of infusion businesses
9 that add value to all infusion products and services and
10:19AM 10 general value to the entire medical practice in many cases.

11 And, in fact, if you do consider the presentations
12 that Janssen has submitted, you can see from those
13 presentations that they don't relate specifically to
14 Janssen's products, the information in those presentations
15 applies generally to practice management.

16 THE COURT: I mean, isn't that sort of the critical
17 issue, like, in other words, whether it has independent
18 value? I mean, sales reps, they used to call them detail
19 men. I'm showing my age here, but, of course, they focus on
10:20AM 20 physicians who are going to prescribe more of the product,
21 and so, you know, a physician in Midtown Manhattan is going
22 to get more attention than somebody in rural Maine, there's
23 no surprise there, but that the issue, is it not the key
24 issue whether this was not simply product support but had
25 independent value? Isn't that the critical inquiry?

1 MR. PRESTON: Yes, your Honor, even if these
2 services were considered to be product support, which,
3 again, we don't believe they are, but if they were
4 considered to be product support, they do have substantial
5 independent value.

6 They confer significant benefit on the physicians
7 that receive them. They have benefit far beyond just use of
8 a product. In fact, they don't relate to the proper
9 administration of Remicade or Simponi ARIA, they relate to
10:21AM 10 operation of an infusion business, operation of a medical
11 practice. The information has as much value to Orencia or
12 Rituxan or other infusible drugs that these physicians
13 utilize than it does to Remicade and Simponi ARIA.

14 Your Honor, returning to the OIG guidance, the OIG
15 guidance sets forth numerous hallmarks and red flags of
16 illegal arrangements that are identified by courts. All
17 those, several of those red flags are present in this
18 arrangement that Janssen has with top in-office infusion
19 suites.

10:22AM 20 The services are provided to doctors who have
21 direct influence on generating business for Janssen. The
22 services increase the use of overutilization and
23 inappropriate utilization. The services take into account
24 sales volume in deciding who receives the services and how
25 much services they receive. The services are far more than

1 trivial in value.

2 The 2003 OIG guidance warns that services, they are
3 only offered to select purchases based on volume of business
4 generated, as is alleged here, are more likely to violate
5 the anti-kickback statute.

6 The 1994 OIG guidance specifically warns that
7 providing free training in areas such as management
8 techniques to induce patient referrals would constitute a
9 suspect set of arrangement.

10:23AM 10 While it's clear from the statute and from the OIG
11 guidance that it constitutes illegal remuneration, the value
12 of services only need to be more than nominal or trivial.
13 The facts alleged by Ms. Long give rise to a strong
14 inference that the services have significant and substantial
15 value.

16 In fact, as the complaint explains, the services
17 have a discernible cash value, the significant amount that
18 Janssen Biotech and physicians pay consultants to provide
19 many of the same services that the area business specialists
10:23AM 20 provide for free. In fact, Janssen Biotech pays outside
21 consultants over \$1,000 per consultative session to provide
22 many of these services to top accounts.

23 Yet, Janssen disregards these allegations and
24 argues that the infusion business support doesn't have
25 independent value apart from Remicade and Simponi ARIA and

1 confers no benefits to physicians. That's just not what the
2 complaint alleges, your Honor.

3 I'd like to address the *Suarez* and *Forney* cases as
4 well as the advisory opinions that Janssen is relying so
5 heavily upon. Your Honor, any examination of those
6 authorities shows that the services at issue in those cases
7 and advisory opinions are just completely different than the
8 business support services that are at issue in this case.

9 In *Suarez*, Abbvie is providing nurses to help
10:25AM 10 patients, not physicians, to help patients properly
11 administer injections of its drug to make sure they are
12 properly trained and knowledgeable about the administration
13 of the drug.

14 Abbvie is not alleged or the relator in that case
15 does not allege that Abbvie is providing business advice,
16 practice management consulting services, anything that
17 remotely resembles what relator alleged Janssen is
18 providing.

19 Janssen's counsel I think misspoke because he
10:26AM 20 reported that the nurses are actually stationed in the
21 physicians' offices, and, therefore, taking the burden off
22 of the staff. That's not accurate. The nurse ambassadors
23 go out to the patients' homes and meet with the patients at
24 their homes and are available by telephone if the patients
25 have questions.

1 The interfacing that the nurse ambassadors are
2 alleged to have with physicians relates to reporting any
3 information about the clinical use of the specific product
4 that the patient may raise with the nurse ambassador, but
5 the nurse ambassadors are not stationed in the physicians'
6 offices, and the nurse ambassadors are not providing advice
7 and assistance on operating the practice or an infusion
8 suite.

9 Your Honor, Janssen's reliance on the *Forney* case
10:27AM 10 is interesting. In that case, the assistance relates to
11 specific cardiac devices, such as pacemakers and
12 defibrillators, and the device manufacturer provides a
13 representative that assists the physician in implanting that
14 device.

15 In addition, the representative follows up with
16 patients to ensure that the device is working properly,
17 performing what are called interrogations, and, yes, in the
18 *Forney* case, it's alleged that the device manufacturer also
19 helped with reimbursement support for their devices.

10:28AM 20 Initially, in that case, the Court ruled that the
21 relator did not satisfy Rule 9(b), but after amendment, the
22 Court held that, in fact, the relator had alleged even those
23 services, which are far different than the services alleged
24 here and are more along the lines of product support. The
25 Court determined and ruled that the relator there had

1 plausibly alleged that those services had independent value
2 and conferred a benefit to the physician.

3 Your Honor, with regard to the advisory opinions, a
4 review of these advisory opinions, the services have nothing
5 to do with business support, and, in fact, not only is
6 Janssen's reliance on them factually inaccurate, the
7 advisory relying on them, it's procedurally inappropriate.

8 These aren't Janssen's advisory opinions.
9 Janssen never sought an advisory opinion regarding this
10 business support.

10:29AM

11 Under HHS regulations, Janssen's barred from using
12 these advisory opinions to try to prove that they didn't
13 violate the anti-kickback statute, and, in fact, citing that
14 regulation, this Court in *U.S. ex rel. Banigan v. Organon*,
15 which is cited in Ms. Long's briefing, refused to consider
16 advisory opinions requested by other entities.

17 Your Honor, I'm now going to turn to this attempt
18 by Janssen to have your Honor assess the value of all the
19 services that Janssen is providing to its top accounts based
20 on a few examples of slide decks that they selected and
21 submitted to the Court.

10:30AM

22 Your Honor, that's just not a fair approach to a
23 factual assessment, and any factual assessment at this stage
24 would be premature. You asked Janssen's counsel whether
25 it's appropriate for the Court to consider these

1 presentations. It would be inappropriate to view these
2 presentations as central or integral to the relator's claims
3 because they represent a small portion of the presentations
4 that were used. These services have been provided, as
5 Ms. Long details in her 120-plus page complaint. These
6 services have been provided going back as far as 2003. She
7 provided them for over 13 years.

8 There are numerous presentations and variations of
9 the presentations, but presentations are just one part of
10 the services they provided. They are, actually, the area
11 business specialists are there hands-on, in-person helpings
12 diagnose practice management issues. They spend more time
13 implementing changes and assistance than they do on a slide
14 deck, which Janssen knows potentially could get into the
15 wrong hands. And the slide decks, again, your Honor, even
16 if they were to be considered, you will see that this is not
17 traditional product support, and the services that are
18 outlined in those particular samples that Janssen Biotech
19 has selected relate to the entire infusion business, entire
20 practice.

21 A factual assessment of the value of the infusion
22 business support requires consideration of other evidence
23 regarding these services value, such as what was
24 management's purpose in providing the service.

25 Ms. Long alleges that the purpose of providing

1 these services was to induce utilization by helping these
2 accounts grow their in-house infusion business, and,
3 therefore, they would in turn grow their use of Remicade and
4 Simponi ARIA.

5 To do a fair factual assessment of the value of the
6 infusion business support services at issue here, then
7 you've got to look at the market value and demand from these
8 services that are provided by other practice management
9 consultants.

10:33AM 10 Janssen wants to act like it is paying these area
11 business specialists, this large team of special employees
12 that this is a team in addition to your traditional sales
13 representatives in addition to your clinical science
14 liaison.

15 Relator isn't aware of any other drug manufacturer
16 employing a team like this that solely are dedicated to
17 helping offices operate their infusion business.

18 They want to act like they've been providing these
19 services for years, but they have no value to physicians,
10:33AM 20 and they've been paying outside consultants top dollar, but
21 those services have no value to physicians.

22 In order to do a fair factual assessment of the
23 value of the infusion business support, you've got to also
24 take a look at defenses and the value that the top 10
25 accounts derive from the services.

1 Janssen's counsel claims that the relators'
2 complaint doesn't set forth any particularity with regard to
3 the services that were provided to specific accounts.
4 That's just untrue.

5 In paragraph 176, the relator provides several
6 examples of accounts that she regularly provided the
7 services to and had those accounts valued the services, and
8 it also talks about how the services had value that went far
9 beyond Remicade and Simponi ARIA and were focused on
10:34AM 10 management of the accounts' infusion businesses.

11 Your Honor, I'm going to turn to Janssen's argument
12 concerning Rule 9(b), and, your Honor, this case in
13 relators' complaint, she alleges with substantial
14 particularity specific accounts, although identified by
15 letter, rather than name, Janssen knows who those accounts
16 are.

17 As is set forth in the complaint and explained in
18 detail, Janssen selects who receives the infusion business
19 support. Janssen closely monitors every account that
10:35AM 20 receives the infusion business support, and, in fact,
21 Janssen follows the results of the infusion support by
22 following how much additional use of Remicade, Simponi ARIA,
23 and other competing infusibles and non-infusibles these
24 accounts use.

25 If Janssen was concerned about the identities of

1 these particular accounts, it could ask for the names of
2 these particular accounts. It hasn't. The relator has that
3 information and is willing to share it, and if your Honor
4 would like that information, I can provide those names to
5 you during this argument, but Janssen knows who those
6 physicians are.

7 Your Honor, in addition to specifying in the
8 complaint the regular services that the relator provided to
9 those accounts, the complaint also pleads CMS data that
10:37AM 10 shows that while those accounts were receiving the free
11 services regularly from the relator, they were also billing
12 Medicare for Remicade.

13 The data is over a long period of time. Not all of
14 the data is available, but based on that data with
15 physicians that received these services, regularly billed
16 for a large volume of Remicade.

17 There's also an example of a physician that billed
18 for a large volume of Simponi ARIA while that physician was
19 regularly receiving the kickbacks from Janssen. Those are
10:38AM 20 false claims.

21 The complaint specifies a patient who received
22 services for infusions of Remicade from a physician who was
23 regularly receiving the kickbacks from Janssen.

24 The complaint sets forth the who, what, when, where
25 of the false claims in great detail, and, in addition, and

1 when the Court applies the First Circuit's, they call it the
2 more flexible approach to 9(b), a 9(b) assessment that was
3 set forth in the *U.S. ex rel. Nargol vs. DePuy Orthopaedics*
4 case. The statistical evidence that is set forth in the
5 complaint clearly shows that, you know, with certainty that
6 the top IOI accounts, who are the biggest market for
7 Remicade and Simponi ARIA, are billing Medicare and Medicaid
8 for infusion services as well as Janssen's drugs while they
9 are receiving the free business support.

10:39AM 10 In addition to that, the complaint alleges facts
11 that show that this is a nation-wide scheme. Relator is one
12 of many ABSs. The ABSs don't act on their own. The ABSs
13 take direction from Janssen's management, and the complaint
14 sets forth in significant detail how Janssen's management
15 has created this ABS program, the alleged anti-kickback
16 scheme, and directs the ABSs to provide the specifics for --
17 it trains them how to provide the services, it closely
18 monitors the ABSs' activities as well as the resulting drug
19 utilization and growth at the recipient's infusion
10:40AM 20 businesses.

21 The complaint describes how the relators' regional
22 manager, who oversaw ABSs in each state, directly
23 participated in providing infusion business support to
24 accounts. These and other alleged facts give rise to a
25 strong inference that Janssen is providing alleged kickbacks

1 and causing false claims to be filed cross country.

2 Janssen's attempt to limit the scope of relators'
3 case to cover all these false claims filed in our
4 territories got to be denied.

5 THE COURT: Okay.

6 MR. PRESTON: Finally --

7 THE COURT: I'm sorry, go ahead.

8 MR. PRESTON: Unlike in cases where discovery was
9 limited to a region, the allegations here are based on
10:41AM 10 Ms. Long's credible firsthand information that Janssen is
11 paying kickbacks to top prescribers of its drugs, not just
12 in her testimony and not just throughout the mid-Atlantic
13 region but nationwide.

14 Janssen's request to limit discovery for Ms. Long
15 has even been afforded an opportunity to present her
16 discovery plan is premature.

17 Your Honor, if you have any questions, I'd be happy
18 to answer them.

19 THE COURT: No, let me hear Mr. Posner's quick
10:41AM 20 response.

21 MR. POSNER: Yes, sure, a couple of things. These
22 arguments are exactly the kind of arguments that were
23 considered in the *Suarez* and *Forney* case and that the OIG
24 grapples with, right? Like the company spends a lot of
25 money on these kind of services.

1 In the *Suarez* case, and, by the way, there was a
2 specific allegation in paragraph 75 of the *Suarez* complaint
3 that the nurses are visiting the doctor's offices. They
4 actually go into the doctor's office and they say, Doc, is
5 there an administration question that you got, so tell us
6 that and we'll go handle it. That's exactly the allegation.

7 And in the *Suarez* case, the nurses were going out
8 to the patients in the doctor's offices and fielding and
9 handling all sorts of administrative questions and billing
10:42AM 10 and coding and reimbursement, and relators always say, well,
11 that costs a lot of money.

12 The question isn't whether it costs money for the
13 company, I'm sure it does, we're not disputing that, the
14 question is is there independent value apart from the
15 product to the doctor, and I think the OIG and the cases say
16 there is not.

17 You know, the other cases also dealt with an
18 allegation, well, you know you're focusing on more
19 significant physicians, and that's what detail men and women
10:43AM 20 have been doing for years, that yes, there's certainly a
21 hope or an expectation that this kind of assistance, you
22 know, may yield a favorable view of the medicine, but that's
23 been true in all of these product support opinion cases.

24 You know, the OIG has just not analyzed these as
25 gifts or payments in kind. Gifts and payments in kind are,

1 you know, cash. The general rule on this, you're not
2 supposed to replace the receptionist at the doctor's office,
3 you're not supposed to provide something that easily can be
4 used for other functions.

5 There's no OIG opinion that says, well, you can
6 provide a computer so long as the computer is linked to your
7 product, and, but, you know, you can't provide sort of a
8 general computer that you'll use 90 percent of the time for
9 other things as sort of a line that the OIG has drawn.

10:44AM 10 And so these kinds of arguments about the company
11 spent a lot of money, they focus on the bigger doctors, they
12 spend a lot of time with the physicians, that was true in
13 *Forney* and *Suarez* and these OIG opinions.

14 These product support services do, in fact, cost
15 these companies a lot of money, reimbursement support,
16 coding support, prior authorization. We're all familiar
17 with the paperwork involved in some of these more high end
18 specialty medicines that are innovative. There's a lot of
19 prior op. and other kinds of requirements, and companies do,
10:45AM 20 in fact, spend a lot of money on assisting patients and
21 doctors through these kind of administrative morass, and
22 they spend a lot of money to do that.

23 And the OIG I think has determined if they are
24 linked to the product, if they really aren't, you know, if
25 they are really just, yes, maybe, you know, in theory they

1 cost the companies a lot of money, as long they are linked
2 to the product, and billing and coding assistance for
3 Remicade doesn't have any particular applicability outside
4 of Remicade, that's -- it's targeted at the product.

5 Now, on paragraph 176 under the 9(b) issue,
6 relators' counsel is correct, 176 does, in fact, describe
7 the services provided to these particular accounts. I mean,
8 I have no idea who these accounts are, but the accounts
9 aren't the -- the identity of the accounts aren't really the
10:45AM 10 problem or the fact that services were provided to them, I'm
11 sure they were.

12 The problem is that all that's in the complaint is,
13 well, they submitted thousands of Medicare and Medicaid
14 claims. I'm not disputing that, I just have no idea how
15 they are linked to this case or what specific claims there
16 are.

17 THE COURT: Okay. Is that it?

18 MR. POSNER: That's it.

19 THE COURT: Last word, Mr. Preston.

10:46AM 20 MR. PRESTON: Your Honor, I think that upon review
21 of the *Suarez* decision and the *Forney* case, including the
22 subsequent decision after the decision that Janssen cited
23 will show that those cases, the service in those cases bare
24 zero resemblance to the services Janssen is providing.

25 The reference to the computer that is at issue in

1 one of the advisory opinions that Janssen improperly relied
2 upon, the services at issue here are in-person,
3 individualized practice management consulting.

4 The fact that OIG would be concerned that a
5 computer, whether that computer allows access to support for
6 other products in addition to the manufacturer's product,
7 who supplied the computer to the physician shows that these
8 services are far more, raise similar, far more concerns
9 about inducing utilization of the product than a computer
10 would.

10:47AM

11 These are again, these are services that help these
12 physicians operate an entire infusion suite and their entire
13 practice. They are not product support. If they are
14 considered to be product support, under the OIG standard for
15 evaluating whether product support constitutes illegal
16 remuneration, the services alleged here easily satisfy that
17 standard. They have independent value beyond
18 Janssen's products, and they confer substantial benefit to
19 the physicians that receive them.

10:48AM

20 MR. POSNER: Your Honor, all I would say, just take
21 a look at page 27 of Exhibit F. It's a public article.
22 It's a lot of consulting advice. I agree it's a lot of
23 consulting advice. It's just free. Thank you, your Honor.

24 THE COURT: All right. Thank you, I will take it
25 under advisement. Thank you. It was well argued on both

1 sides, and, again, I'll take it under advisement, and we'll
2 stand in recess. Thank you.

3 (Whereupon, the hearing was adjourned at
4 10:49 a.m.)

5 C E R T I F I C A T E

6
7 UNITED STATES DISTRICT COURT)
8 DISTRICT OF MASSACHUSETTS) ss.
9 CITY OF BOSTON)

10 I do hereby certify that the foregoing transcript,
11 Pages 1 through 31 inclusive, was recorded by me
12 stenographically at the time and place aforesaid in Civil
13 Action No. 16-12182-FDS, THE UNITED STATES OF AMERICA ex rel.
14 JULIE LONG vs. JANSSEN BIOTECH, INC., and thereafter by me
15 reduced to typewriting and is a true and accurate record of the
16 proceedings.

17 Dated May 11, 2023.

18 s/s Valerie A. O'Hara

19

VALERIE A. O'HARA
20 OFFICIAL COURT REPORTER
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